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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,857

07/10/2006

Stephen R. Madaus

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EXAMINER

WON, BRIAN D

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,857	<b>Applicant(s)</b> MADAUS ET AL.	
	<b>Examiner</b> BRIAN WON	<b>Art Unit</b> 3771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07/13/09.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/09/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I in the reply filed on 07/13/09 is acknowledged.
2. Claims 16-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/13/09.

### *Drawings*

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the headband arrangement used to furnish a gas outflow area in claims 6-7, the supporting wall structures in claims 11-12, and a conduit unit in communication with a mask interior defined by the respiratory mask, in such a manner that an outflow from the mask interior of respiratory gas that is under pressure can be effected through the air permeable material portion provided in the headband in claim 15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

Art Unit: 3771

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Claim Objections***

4. Claim 2 is objected to because of the following informalities: Gore-Tex is a trademark and it should be capitalized wherever it appears and be accompanied by the generic terminology. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claim 7, it unclear how the headband arrangement

Art Unit: 3771

is used to furnish a gas outflow area. Regarding claims 11-12, it is unclear how the supporting wall structures deploy the covering device and form part of a skeletal structure. Regarding claim 15, it is unclear how an "outflow from the mask interior of respiratory gas that is under pressure can be effected through the air-permeable material portion provided in the headband".

7. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claim 15, it is unclear how "a headband arrangement" is used to perform the claimed function.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, "a respiratory gas evacuation device" is misdescribed. Is the respiratory gas evacuation device used for evacuating respiratory gas or delivering? Also, "this mask interior" is unclear. Examiner suggests --the mask interior--. Claim 1 recites the limitation "the facial surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 3771

Regarding claim 4, it is unclear if the applicant is claiming an apparatus or a method of making. Also it is unclear what the "influence of pressure" is and what disclosed structure forms the claimed pressure. Claim 4 recites the limitation "the influence of pressure" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 5, it is unclear what is meant by "a sufficient outflow of gas from the mask is assured". Claim 5 recites the limitation "the air-permeable material" and "the area of the portion" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 7, term "likewise" is unclear and it is unclear what is meant by "furnish a gas outflow area". Claim 7 recites the limitation "the headband arrangement" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 8, it is unclear how the sealing lip device is "sprayed" onto the covering device.

Regarding claims 11-12, it is unclear what "supporting wall structures" are and what the relationship is between the respiratory mask arrangement.

Regarding claim 12, it is unclear what "skeletal structure" is. Claim 12 recites the limitation "the supporting wall structures" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the woven outlet portion" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 3771

Regarding claim 15, it is unclear what is meant by "pressure can be effected through the air-permeable material portion". Claim 15 recites the limitation "the headband" in line 5. There is insufficient antecedent basis for this limitation in the claim.

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation air-permeable woven material, and the claim also recites Gore-Tex which is the narrower statement of the range/limitation.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3771

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 3, 5-7 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Drew (EP1314445).

Regarding claim 1, Drew discloses in figure 3, a respiratory mask arrangement having a sealing lip device (12, 64) for resting on the facial surface of a mask user, a covering device (28) which in cooperation with the sealing lip device defines a mask interior, a respiratory gas evacuation device for delivering respiratory gas to the mask interior defined by the covering device, the mask interior communicating with the nostril and oral opening of the mask user, the covering device is made from a GORE-TEX material (see pg. 5, lines 4-5).

Regarding claim 3, Drew discloses the covering device (28) being a GORE-TEX material, a porous material.

Regarding claim 5, Drew discloses the covering device (28) for sufficient outflow of gas from the mask interior.

Regarding claim 6, the covering device of Drew is considered elements 12 and 28, which is coupled with a headband arrangement at extension (66) (see para. 41).

Regarding claim 7, Drew, as best understood discloses a headband arrangement headband arrangement used to furnish a gas outflow area (the headband must be used to attach the mask to the user in order for the gas to flow outside of covering device).

Regarding claim 10, figure 3 of Drew discloses the sealing lip device (12, 64) being integral with the covering device (28).



Art Unit: 3771

Regarding claims 11-12, as best understood by the examiner, Drew discloses supporting wall structures (26) forming part of skeletal structure, for deploying the covering device (28).

Regarding claim 13, the covering device of Drew is considered elements 12 and 18. Drew discloses the covering device having a hard shell body (12) and a woven outlet portion (28) coupled to the hard shell body.

Regarding claim 14, Drew discloses the woven outlet (28) portion having an area of 481 mm<sup>2</sup> (see para. 44).

Regarding claim 15, as best understood by the examiner, Drew discloses a headband arrangement (12, 26, 28, 66) for a respiratory mask (60), the headband arrangement having an air-permeable material (28) (GORE-TEX) and including a conduit unit (62) in communication with a mask interior defined by the respiratory mask, such that an outflow from the mask interior of respiratory gas that is under pressure is effected through the air-permeable material portion (28) provided in the headband.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 3771

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 4 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drew (EP1314445).

Regarding claim 4, Drew discloses the covering device being a GORE-TEX material, a flexible material, deployed in the mask interior. Although Drew doesn't specifically teach the step of the flexible material being deployed in the mask interior under the influence of pressure, an ordinary person in the skilled of art would've been able to provide the covering device by deploying the mask interior by pressure which merely considered a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such method.

Regarding claim 8, Drew discloses sealing lip device (12, 64) but does not specifically mention that the sealing device being glued, vulcanized or sprayed onto the covering device, However, the feature of choosing the sealing lip device to be glued, vulcanized or sprayed is merely a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the sealing lip device by gluing, vulcanizing or spraying for better attachments between the covering device and sealing lip device.

Art Unit: 3771

Regarding claim 9, Drew discloses that the covering device can be detachably coupled in a different embodiments (see fig. 8) but does not specifically mention that the covering device of figure 3 is detachably coupled with the sealing lip device. However, one in ordinary skill in the art would be able to provide the covering device in figure 3 to be detachably coupled with the sealing lip device since figure 8 of Drew already discloses the covering device being detachable.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ward (4458679) discloses a respiratory mask having a permeable covering device (GORE-TEX). Metcalfe (6513588) teaches that a GORE-TEX is a flexible and porous material (see col. 3, lines 46-52).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN WON whose telephone number is (571)270-7129. The examiner can normally be reached on Monday thru Friday, 9:00 A.M to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN WON/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771